TENT COOPERATION TRE Y

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 04 March 2000 (04.03.00)	
International application No. PCT/GB99/02381	**Applicant's or agent's file reference** JL2164
International filing date (day/month/year) 22 July 1999 (22.07.99)	**Priority date** (day/month/year) 22 July 1998 (22.07.98)
Applicant CANHAM, Leigh, Trevor et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:
15 February 2000 (15.02.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer S. Mafla
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

Form PCT/IB/331 (July 1992)

3144708

PATENT COOPERATION TREATY

REC'D 19 OCT 2000
WIPO PCT

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
JL2164		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB99/02381	22/07/1999	22/07/1998
International Patent Classification (IPC) or national classification and IPC B81B1/00		
Applicant THE SECRETARY OF STATE FOR DEFENCE et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
15/02/2000	17.10.2000
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Kusztelan, L Telephone No. +49 89 2399 2479

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB99/02381

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-39	as originally filed				

Claims, No.:

1-36	as received on	08/08/2000	with letter of	04/08/2000	

Drawings, sheets:

1/9-9/9	as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims 1,8
	No:	Claims 36
Inventive step (IS)	Yes:	Claims 17
	No:	Claims 1,8
Industrial applicability (IA)	Yes:	Claims 1-36
	No:	Claims

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Section V

1. Reference is made to the following document/s/:

   D1: US5137817
   D2: US5383512
   D3: US5262128
   D4: US96/07395
   D5: US5457041
   D6: WO97/04297

2. The present application does not satisfy the criterion set forth in Art. 33(2) PCT because the subject-matter of claim 36 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3)).

2.1 Product claim 36 is defined in terms of a "product by process" feature cf. "fabricated according to the methods of any one of claim 1 to 35". Such a formulation is only allowable if the product arising from any of these methods is distinguishable from the micro-needle of the prior art.

In the present case, there are three methods, cf. claims 1,8 & 17 of making the micro-needle which are quite distinct, by inspection; the methods of claims 1 & 8 provide a ducted needle of silicon material, being the same as the substrate material whilst the method of claim 17 is directed to providing a ducted needle of different material to that of the substrate, viz. any material i.e. the needle material of claim 36 is not specified. Moreover, the processes of manufacture involving removal of surrounding substrate or needle material deposition are such that an unambiguous structural feature of the end product is not evident. Accordingly, the distinguishable feature of the device of claim 36 is "A micro needle".

This subject-matter is, however, not novel for the following reasons:

D1, cf. Figs. 4C,4F & corresponding Text discloses a micro-tube (20,37) fabricated onto the surface of a first material (12).

Further documents D2, cf. Figs. 2A-2C & corresponding Text, D3, cf. Fig.4 & corresponding Text & col.2 lines 17-53, D4, cf. Fig.1 & corresponding Text, D5, cf. Figs.4A,4B & corresponding Text & D6, cf. Figs.2B,2C & corresponding text also take away the novelty of the claimed subject-matter, by inspection.

Having regard to the nature of the above objection, it does not appear that an allowable device claim can be formulated.

3. The present application does not satisfy the criterion set forth in Art. 33(3) PCT because the subject-matter of claims 8 & 1 does not involve an inventive step in respect of prior art as defined in the regulations (Rule 64(1)-(3)).

3.1 Regarding claim 8, attention is drawn to the claimed feature "a duct in at least a region of said tip", i.e. not necessarily extending through the entire needle tip, which is also supported by the description, cf. Fig.16 & associated text. The subject-matter of this claim is not inventive with regard to D5, for the following reason:

D5, cf. Fig.5 & corresponding text inc. col.8 line 52 to col.10 line 15, discloses a method of providing a silicon micro-needle (12), the micro-needle having a base adjoining a silicon substrate (16), a tip (28) remote from said base and a duct in at least a region of said tip (inc. col.7 line 58 "hollow or concave" i.e. a duct region), the method comprising:

a. selectively removing the silicon substrate to provide a micro needle (cf. col.8 line 59 to col.9 line 55)
b. providing a duct coincident with the micro-needle.

Accordingly, the claimed matter differs from that of D5 in that step (b) is subsequent to step (a). The skilled person, on reading the col.8 text immediately realises that the needle tip region is covered with the silicon dioxide pattern, which clearly must be removed, subsequent to any hollow formation (this being done by etching). Since a two step nature of the D5 process immediately follows, an inventive nature is not appreciated.

3.2 For completeness, a futher objection of lack of inventive step of claim 8 is made having regard to D3, cf. Fig.4 & corresponding text, particularily col.6 lines 55-57. In this regard, it is apparent to the skilled person from the text of D3 (cf. col.4 line 56 to col.5 line 13) & knowing that "micromachining a silicon chip utilising techniques well known in the integrated circuit industry", will thus actively seek such techniques to fabricate microneedles (their angle to the substrate not being specified in the claim) i.e. adapt the "Liga" process accordingly, knowing that this process is suited to a wide variety of materials and, in particular, that lithography & etch of semiconductors (also being metallic when doped) & metals is equally possible.

3.3 Having regard to claim 1, it is apparent to the skilled person that the method disclosed in D3, Fig.4 & corresponding text, cf. col.4 line 56 to col.5 line 13 as well as col.6 lines 55-58 also provides a silicon micro needle comprising providing a ducted silicon substrate, cf. also the references to the "liga" process of Section 3.2, an inventive nature of this subject-matter being not determined.

4. The present claims 1,8 & 36 are not allowable for these reasons.

Section VII

The documents D1-D6 have not been identified in the description nor has the relevant prior art disclosed therein been discussed. The requirements of Rule 5.1(a)(i) PCT are therefore not fulfilled.

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Section VIII

1. Having regard to a patentable nature of the subject-matter of the application, it appears that a claim 17, clarified to render the order of the process steps unambiguous (the present amended form comprises any order) is not known from

or is obvious with regard to the available search documentation. In particular, closest prior art D1, discloses a two material microneedle fabrication process in which the duct evidently may only be formed after the second material is deposited i.e. the known process is not adaptable to forming a duct as claimed in a clarified claim 17 process.

Having regard to the additional subject-matter of claims 2-7 & 9-16, this matter is known from D1,D2,D3 & D5, cf. above citations and therefore could not be considered new or inventive.

2. For completeness, the common concept linking the claims 1,8 & 17 viz. providing a microneedle with a duct is known from any of D1,D2,D3 & D5, cf. above citations, giving rise to an objection of lack of unity, R13(1) PCT.

CLAIMS

1. A method of providing a micro-projection on the surface of a first material, the micro-projection having a base portion adjacent the first material and a remote, or a tip portion, and a duct at least in a region of the tip portion and the method comprising micro-machining the first material to provide the micro-projection and duct.

2. A method according to claim 1 in which the duct passes between the tip portion and the base portion.

3. A method according to claim 1 or 2 in which the duct passes entirely through the micro-projection.

4. A method according to any preceding claim in which the base portion has a width of less than approximately 1000μm.

5. A method according to any preceding claim in which the duct is fabricated to be coincident with an apex of the micro-projection.

6. A method according to any preceding claim in which the duct is fabricated in a piece of the first material and subsequently the micro-projection is fabricated in the first material such that the micro-projection is co-incident with the duct.

7. A method according to any preceding claim in which a masking layer is formed on to the surface of the first material.

8. A method according to claim 7 in which the masking layer comprises silicon dioxide.

9. A method according to claims 7 or 8 in which an aperture is formed into the masking layer using lithographic techniques.

10. A method according to claim 9 in which the first material is removed from a region underneath the aperture in the masking layer to form a duct.

11. A method according to any of claims 6 to 10 in which the micro-projection is formed by any of the following techniques: a) anisotropic wet etching of silicon using liquid alkaline etches; b) focused ion beam milling; or c) transferring a pattern to the first material from a domed region of the masking layer using plasma/ion beam etching.

12. A method according to any of claim 7 to 10 in which the masking layer is removed from the first material.

13. A method according to claim 12 in which a second masking layer is created on the first material after the removal of the first masking layer.

14. A method according to claim 13 in which the second masking layer is silicon dioxide.

15. A method according to claim 13 or claim 14 in which the first material is etched using an anisotropic etch which undercuts the masking layer.

16. A method according to claim 15 in which the crystal planes of the first material are arranged so that planes having a low etch rate bound the etching process creating the desired micro-projection structure.

17. A method according to claims 15 or 16 in which the second masking layer is then removed.

18. A method according to claim 13 or claim 14 in which a portion of the second masking layer covering the top surface of the first material is removed so as to leave the second masking layer covering the inside surface of the duct.

19. A method according to claim 18 in which the first material is then removed from around the second masking layer on the inside surface of the duct leaving the masking layer substantially intact.

20. A method according to claim 19 in which the micro-projection is fabricated from a second material which is different from that of the first material.

21. A method according to claim 18 in which a portion of the second masking layer covering of the inside surface of duct is removed before the first material is removed from around the second masking layer.

22. A method according to any of claims 18 to 21 in which the cross section of the micro-projection is defined by the cross section of the duct.

23. A method according to any of claims 18 to 22 in which the cross section of the duct is circular, square, rectangular, or elliptical.

24. A method according to any of claims 18 to 23 in which the second masking layer is SiO_2, a metal, ceramic, or a polymer or a semiconductor.

25. A method according to any of claims 1 to 5 in which the method comprises fabricating the micro-projection from the material and subsequently forming the duct through the micro-projection.

26. A method according to claim 25 in which, as the first step of the process, a masking layer is created on to the surface of the first material.

27. A method according to claim 26 in which the masking layer is substantially in the shape of a square, or a modified square.

28. A method according to claim 26 or 27 in which the masking layer is silicon dioxide.

29. A method according to any of claims 25 to 28 in which the first material is etched using an anisotropic etch which undercuts the masking layer.

30. A method according to claim 29 in which the crystal planes of the first material are arranged so that planes having a low etch rate bound the etching process creating the desired micro-projection structure.

31. A method according to any of claims 25 to 30 in which the duct is fabricated such that the duct is coincident with an apex of the micro-projection.

32. A method according to any of claims 25 to 28 in which the micro-projection is formed by one of the following techniques: a) anisotropic wet etching of silicon using liquid alkaline etches; b) focused ion beam milling; or c) transferring the pattern to the silicon from a domed resist mask using some form of plasma/ion beam etching.

33. A method according to claims 29 or 30 in which the remaining first material is covered in a planarising layer.

34. A method according to claim 33 in which the planarising layer is patterned using lithography and etched to reveal a portion of the first material.

35. A method according to claim 34 in which the portion of the first material which has been revealed has a maximum cross sectional area, taken normal to its axis, substantially equal to the cross sectional area, taken normal to its axis, of the duct to be formed.

36. A method according to claim 38 or 39 in which once the portion of the first material has been revealed the duct is etched.

37. A method according to any preceding claim in which once the micro-projection and duct have been created the method further includes linking the duct to a reservoir.

38. A method according to claim 37 in which a portion of the first material is removed from a side opposite a side of the first material where the micro-projection has been fabricated.

39. A method according to claims 37 or 38 in which the first material is attached to a second piece of material.

40. A method according to claim 39 in which the second piece of material has a channel which connects to the duct and links the duct to a reservoir.

41. A method according to claim 39 or claim 40 in which the first material has a channel which connects to the duct and links the duct to a reservoir.

42. A method according to any one of claims 39 to 41 in which the two pieces of material are fabricated from same material.

43. A method according to any preceding claim in which the surface of the material of the micro-projection is modified.

44. A method according to claim 43 in which the surface of the material of the micro-projection is porosified.

45. A method according to claim 44 in which the porosification is performed by electrochemical anodisation processes or by immersing the structure into a stain etching solution.

46. A method according to any preceding claim in which the micro-projection is fabricated substantially normal to the surface of the first material.

47. A method according to any of claims 1 to 46 in which the micro-projection is fabricated inclined at an acute angle relative to the surface of the first material.

48. A method according to any preceding claim in which one of the following etching techniques is used to etch the duct: a) deep dry etching wherein the planarising layer acts as a mask; b) anodisation of the structure; c) laser ablation; or d) focused ion beam milling.

49. A method according to claim 48 in which anodisation of the structure takes place using an HF containing solution.

50. A micro-projection having a base portion which is provided on the surface of a first material, and a remote, or a tip, portion wherein the micro-projection has a duct at least in a region of the tip portion.

51. A micro-projection according to claim 50 in which the duct passes between the tip portion and the base portion.

52. A micro-projection according to claim 50 or 51 in which the duct passes entirely through the micro-projection.

53. A micro-projection according to any of claims 50 to 52 which is a micro-needle, a micro-barb or a micro-tube, micro-cuvette, a micro-conduit, micro-connector, micro-rod or the like.

54. A micro-projection according to any of claims 50 to 53 in which the base portion has a width of less than approximately 1000μm.

55. A micro-tube fabricated onto the surface of a first material.

56. A micro-tube according to claim 55 in which the micro-tube has base portion with a width of less than approximately 1000μm.

57. A micro-tube according to claims 55 or 56 in which the micro-tube is fabricated from a substance other than that of the first material.

58. A micro-tube according to claim 55 in which the first material is silicon and the micro-tube is fabricated from one of the following materials: SiO_2, a metal, a ceramic, or a polymer, or a semiconductor, or a plastics material.

59. A micro-tube according to any of claims 55 to 58 in which the micro-tube has substantially one of the following cross sections: square, rectangular, circular, elliptical.

60. A micro-tube according to any of claims 55 to 59 which comprises a micro-cuvette.

61. A micro analysis system in which a micro tube according to any of claims 55 to 60 is provided and in which an analysis means is provided to analyse a substance within the micro tube.

62. A micro analysis system according to claim 61 which comprises more than one micro tube.

63 A micro analysis system according to claim 60 or 62 which comprises a delivery means allowing chemicals, or other substances to be delivered into the micro tube.

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WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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A1

(11) International Publication Number: WO 00/05166

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9815820.7 22 July 1998 (22.07.98) GB

22 Jan 2001 | 30 mth

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(72) Inventors; and

(75) Inventors/Applicants (*for US only*): CANHAM, Leigh, Trevor [GB/GB]; Dera Malvern, St. Andrews Road, Malvern, Worcestershire WR14 3PS (GB). COX, Timothy, Ingram [GB/GB]; Dera Malvern, St. Andrews Road, Malvern, Worcestershire WR14 3PS (GB). REEVES, Christopher, Leslie [GB/GB]; Dera Malvern, St. Andrews Road, Malvern, Worcestershire WR14 3PS (GB).

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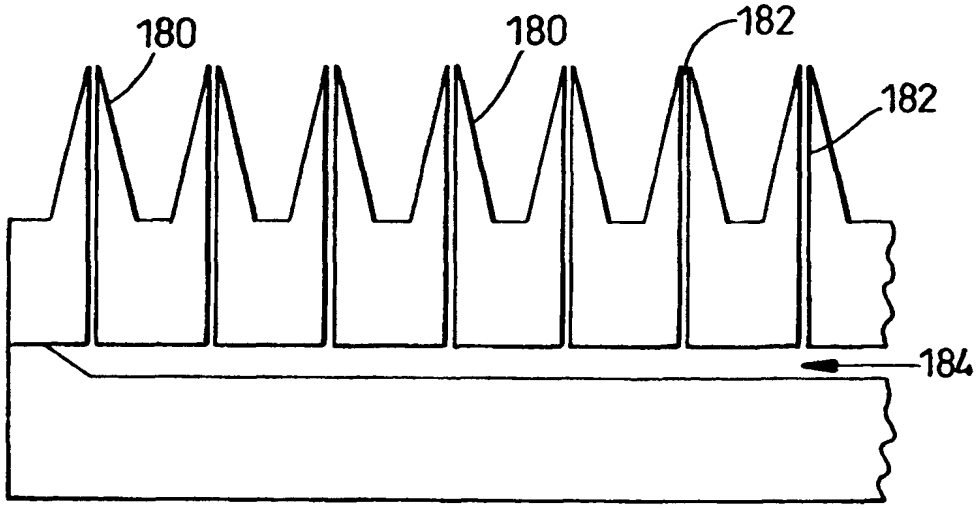
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: SILICON MICRO–MACHINED PROJECTION WITH DUCT



(57) Abstract

A method of providing a microprojection (180) on the surface of a first material, the microprojection having a base portion adjacent the first material and a remote, or a tip portion, and a duct (182) at least in a region of the tip portion and the method comprising micro–machining the first material to provide the micro–projection duct. Various uses of the microprojection are also disclosed including light guides and cuvettes from micro–analytical systems, microneedles for transdermal fluid delivery or the like.

INTERNATIONAL SEARCH REPORT

Ir. ational Application No
PCT/GB 99/02381

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 B81B1/00 B81C1/00 G01N21/03

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12M G01N B01L B01J A61M B81B B81C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 04297 A (NORTHEASTERN UNIV) 6 February 1997 (1997-02-06)	50-56,59
A	page 1, line 31 -page 3, line 35 page 10, line 7 -page 11, line 3 figures 1A,1B,2B,2C	61-63
X	US 5 137 817 A (BUSTA HEINZ H ET AL) 11 August 1992 (1992-08-11) column 10, line 39 -column 11, line 14; figures 4C,4F,4G	50-57,59
X	WO 96 37256 A (SILICON MICRODEVICES INC; GODSHALL NED A) 28 November 1996 (1996-11-28) page 5, line 1 -page 6, line 21 claims 1-5; figure 1	50-56, 58,59

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 November 1999	23.12.99

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax (+31–70) 340–3016	Köpf, C

Form PCT/ISA/210 (second sheet) (July 1992)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1-49

The term "micro-machining" has no well established meaning in the art: It describes a generic technology which may use a huge number of different techniques or combinations of techniques. Furthermore it is excessively relative due to the prefix "micro". At the other end it obviously appears that a process for fabricating a -micro-projection must use -micro-fabrication techniques, and consequently -micro-machining of materials.

Additionally it is noted that the document US 5 262 128, acknowledged in the application and mentioned as being unsuitable to fabricate the microprojections in question, discloses in col. 6 the formation of a microprojection using etching techniques, which fall into the generic term "micro-machining". Hence the meaning of the term "micro-machining" in the context of the present application and the different techniques or combinations of techniques it may encompass is especially obscure and does not appear limited. It follows that the scope of claim 1 is unclear and not sufficiently defined, contrary to the requirements of Art. 6 PCT.

Consequently a meaningful search cannot be carried out for the claims 1-49 (Art. 17(2)(a) PCT). The search is therefore limited to the claims 50-63 (Art. 17(2)(b) PCT).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
JL2164		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB 99/02381	22/07/1999	22/07/1998
Applicant		
THE SECRETARY OF STATE FOR DEFENCE et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

   [ ] the text is approved as submitted by the applicant.

   [X] the text has been established by this Authority to read as follows:

   SILICON MICRO-MACHINED PROJECTION WITH DUCT

5. With regard to the **abstract**,

   [ ] the text is approved as submitted by the applicant.

   [X] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 13

   [ ] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [X] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 99/02381

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 1-49
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Continuation of Box I.2

Claims Nos.: 1-49

The term "micro-machining" has no well established meaning in the art: It describes a generic technology which may use a huge number of different techniques or combinations of techniques. Furthermore it is excessively relative due to the prefix "micro". At the other end it obviously appears that a process for fabricating a -micro-projection must use -micro-fabrication techniques, and consequently -micro-machining of materials.

Additionally it is noted that the document US 5 262 128, acknowledged in the application and mentioned as being unsuitable to fabricate the microprojections in question, discloses in col. 6 the formation of a microprojection using etching techniques, which fall into the generic term "micro-machining". Hence the meaning of the term "micro-machining" in the context of the present application and the different techniques or combinations of techniques it may encompass is especially obscure and does not appear limited. It follows that the scope of claim 1 is unclear and not sufficiently defined, contrary to the requirements of Art. 6 PCT.

Consequently a meaningful search cannot be carried out for the claims 1-49 (Art. 17(2)(a) PCT). The search is therefore limited to the claims 50-63 (Art. 17(2)(b) PCT).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The abstract is changed as follows:

A method of providing a microprojection (180) on the surface of a first material the microprojection having a base portion adjacent the first material and a remote, or a tip portion, and a duct (182) at least in a region of the tip portion and the method comprising micro-machining the first material to provide the micro-projection duct. Various uses of the microprojection are also disclosed including light guides and cuvettes for micro-analytical systems, microneedles for transdermal fluid delivery or the like.

To be accompanied, when published, by Figure 13 of the drawings.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 99/02381

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 B81B1/00 B81C1/00 G01N21/03

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12M G01N B01L B01J A61M B81B B81C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 04297 A (NORTHEASTERN UNIV) 6 February 1997 (1997-02-06)	50-56,59
A	page 1, line 31 -page 3, line 35 page 10, line 7 -page 11, line 3 figures 1A,1B,2B,2C	61-63
X	US 5 137 817 A (BUSTA HEINZ H ET AL) 11 August 1992 (1992-08-11) column 10, line 39 -column 11, line 14; figures 4C,4F,4G	50-57,59
X	WO 96 37256 A (SILICON MICRODEVICES INC; GODSHALL NED A) 28 November 1996 (1996-11-28) page 5, line 1 -page 6, line 21 claims 1-5; figure 1	50-56, 58,59

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
9 November 1999	23. 12. 99

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Köpf, C

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 99/02381

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 262 128 A (LEIGHTON STEPHEN B ET AL) 16 November 1993 (1993-11-16) cited in the application column 2, line 17 - line 52 column 4, line 56 -column 5, line 13 figure 4	50-56, 58,59
X	US 5 383 512 A (JARVIS ERIC E) 24 January 1995 (1995-01-24) column 3, line 42 -column 4, line 60; figure 2	50-56,59
X	US 5 457 041 A (GINAVEN ROBERT O ET AL) 10 October 1995 (1995-10-10) column 7, line 3 - line 65	50,53,54
A	CAICAI WU ET AL: "Oxyhemoglobin measurement of whole blood specimens in a silicon microfabricated cuvette" MICRO- AND NANOFABRICATED ELECTRO-OPTICAL MECHANICAL SYSTEMS FOR BIOMEDICAL AND ENVIRONMENTAL APPLICATIONS, SAN JOSE, CA, USA, 10-11 FEB. 1997, vol. 2978, pages 155-164, XP000852960 Proceedings of the SPIE - The International Society for Optical Engineering, 1997, USA ISSN: 0277-786X abstract section 2.1. Experimental apparatus	55,60-63

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 99/02381

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9704297 A	06-02-1997	CA 2227331 A	06-02-1997
		EP 0840886 A	13-05-1998
		US 5872010 A	16-02-1999
US 5137817 A	11-08-1992	NONE	
WO 9637256 A	28-11-1996	AU 5869796 A	11-12-1996
US 5262128 A	16-11-1993	AU 6640190 A	16-05-1991
		EP 0497885 A	12-08-1992
		WO 9105519 A	02-05-1991
US 5383512 A	24-01-1995	NONE	
US 5457041 A	10-10-1995	NONE	